

## United States Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,867	02/04/2002	Halle Morton	999710000008	3108
7590 10/05/2004			EXAMINER	
Kate H Muras	hige		ANDRES, JANET L	
Morrison & Foo	erster			
Suite 500			ART UNIT	PAPER NUMBER
3811 Valley Center Drive			1646	
San Diego, CA	92130-2332			
			DATE MAILED: 10/05/200/	1

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary    Examiner		Application No.	Applicant(s)					
Janet L. Andres   Janet L. A		09/889,867	MORTON ET AL.					
The MALING DATE of this communication appears on the cover sheet with the correspondence address → Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Exercises of time may be available under the provincies of 3 CFR 1.13(a), in no overt, towever, may a reply be timely filled under \$1X (9) ACMTHS from the mailing date of the communication.  Exercises of time may be available under the provincies of 3 CFR 1.13(a), in no overt, towever, may a reply be timely filled under \$1X (9) ACMTHS from the mailing date of the communication.  If NO period to reply is specified tower, the maintain adultable period vall again and the state of the communication.  If NO period to reply is specified than there no chies are the remaining date of this communication, even if filming filled, may reduce any counter plated from adjustment. See 3 CFR 1.70(b).  Status  1)  Responsive to communication(s) filled on 05 November 2003.  2a)  This action is FINAL.  2b)  This action is FINAL.  2b)  This action is non-final.  3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)  Claim(s)  1-24 is/are pending in the application.  4a) Of the above claim(s)  12-24 is/are withdrawn from consideration.  5)  Claim(s)  1-11 is/are rejected.  7)  Claim(s)  1-11 is/are rejected.  7)  Claim(s)  1-11 is/are rejected.  7)  Claim(s)  1-12 is/are rejected.  7)  Replication Papers  9)  The specification is objected to by the Examiner.  10)  The drawing(s) filled on  is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in aboyance. See 37 CFR 1.121(d).  11)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  2)  Autor of the certified copies of the priority documents have been received.  2.  Ce	Office Action Summary	Examiner	Art Unit					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.736(a). In no overal, however, may a reply be limity filed  Extensions of time may be available under the provisions of 37 CFR 1.736(a). In no overal, however, may a reply be limity filed  Extensions of time may be available under the provisions of 37 CFR 1.736(a). In no overal, however, may a reply be limity filed  Extensions of time may be available under the provisions of 37 CFR 1.736(b). In 17 MO period to reply is pacified above, the maximum statutory period will apply available under SIX (b) MC27115 from the maining date of this communication. Provision for early supported the first of the maximum statutory period will apply available of this communication. Provision for the maining date of this communication. Provision for the provision of the provision o		Janet L. Andres	1646					
THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be sublished under the provision of 37 CPR 1.18(g). In no event, however, may a reply be timely filed after SIX (8) MONTHS from the mailing filed of this communication.  If the pend for crypt specified actives is less than they (8) days, a reply white the statebory minimum of thirty (30) days will be considered fromly.  Failure be reply within the solve or betreided promoted for reply well. In yellowing within the solve to retrieve the promoted of the communication.  Failure be reply within the solve or betreided promoted for reply well. In yellowing within the solve promoted by the Office file that have more made after the maining date of this communication, even if smoly filed, may reduce any commind potent form adjustment. See 37 CFR 1.794(s).  Status  1)								
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## RESPONSE TO AMENDMENT

1. Applicant's amendment filed 5 November 2004 is acknowledged. Claims 1-24 are pending in this office action. Claims 12-24 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

## Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment and provision of a sequence disc.

## Claim Rejections Maintained

3. The rejection of claims 1-11 under 35 U.S.C. 103(a) as unpatentable over Morton et al. in view of the M.S. Study is maintained for reasons of record in the office action of 5 August 2003.

Applicant has amended to claims to require a greater effect than when the two agents are administered separately. Applicant argues that the discovery that the two agents act through different pathways results in a synergistic effect that allows administration of IFN-beta at lower doses. Applicant argues that there is no motivation in the prior art to achieve for this greater effect. Applicant further argues that this effect is unexpected from the teachings of the prior art.

Applicant's arguments have been fully considered but have not been found to be persuasive. Figures 8 and 9, which are the two figures that compare combinations to individual administration, do not indicate that there is any unexpected benefit from this combination. The artisan would expect at least an additive effect and the data show very little advantage to the combination. Figure 8 shows an uneven progression with substantial overlap in the methods of treatment. Figure 9 shows a very modest difference. There is no evidence of a synergistic effect.

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Thus there is no teaching of a result that would be unexpected from the combination of two agents that are useful for the same purpose, which combination is itself *prima facie* obvious for the reasons set forth in the previous office action. There is further nothing in the claims that provides for the reduced administration of IFN-beta; the doses that are provided are those commonly used for IFN-beta. Thus Applicant's specification fails to distinguish the invention from what would be prima facie obvious from the teachings of Morton et al. and the M.S. Project.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D. 30 September 3004

JANET ANDHES
PRIMARY EXAMINER